IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Toby Freyman, Timothy J. Mickley, Maria J. Palasis and Wendy Naimark**
Application No.:	**10/645653**
Filed:	**August 20, 2003**
For:	**Medical Device with Drug Delivery Member**
Examiner:	**Catherine Witczak**
Group Art Unit:	**2855**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-14157-US01

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application for which claims 25-40 are pending in the application and were finally rejected in the office action dated May 28, 2008.

A Notice of Appeal was filed in this case on September 29, 2008. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-0350 for any other fees which may be due with this appeal.

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(i) Real Party in Interest

The application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 25-40 are pending in the application and have been twice or finally rejected. Claims 1-24 are canceled as being drawn to a non-elected invention. Claims 25-40 are being appealed.

(iv) Status of Amendments

All amendments have been entered to date. A Notice of Appeal and Reasons for Pre-Appeal Conference were filed on September 29, 2008.

(v) Summary of Claimed Subject Matter

A summary of representative independent claims as required by 37 C.F.R. §41.37(c)(I)(v) and any dependent claims argued separatel and a non-limiting listing of' locations where support may be found [bracketed citations] referring to the specification by page and line number, and to any drawing, is provided as follows:

Independent claim 25 is directed to an embodiment of a medical device for delivering a therapeutic agent to an internal portion of a patient's body. The medical device includes a shaft and a self-expanding delivery member in operative communication with the shaft. In this embodiment, the delivery member has a proximal end and a distal end and being shaped in a continuous solid cylindrical configuration from a porous material. The porous material is capable of releasing the therapeutic agent to the internal portion of the patient's body and being in a collapsed state. The medical device may further includes a therapeutic agent delivery lumen defined by a lumen wall in which the lumen is in fluid communication with the delivery member to fluidly connect the delivery member with a therapeutic agent source. A retention member is provided in operative communication with the delivery member, the retention member being configured and arranged to selectively collapse the delivery member. and a mechanism capable of applying negative pressure through the therapeutic agent delivery lumen to remove fluid from the delivery member [paragraph [0007]; paragraph [0009]; and claim 25 as filed].

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the Examiner erred in rejecting claims 25-40 under 35 U.S.C. §103(a) as being obvious over Clark et al. (US 5,713,853) as modified by Ding et al. (US 6,364,856).

(vii) Argument

A. Brief Summary

I. The Examiner erred in rejecting claims 25-40 under 35 U.S.C. §103(a) as being obvious over Clark et al. (US 5,713,853) as modified by Ding et al. (US 6,364,856).

B. Detailed Argument

I. The Examiner erred in rejecting claims 25-40 under 35 U.S.C. §103(a) as being obvious over Clark et al. (US 5,713,853) as modified by Ding et al. (US 6,364,856).

It was asserted in the Final Office Action dated 5/28/2008, that:

> … Clark et al. disclose in Figures 24-26 a medical device comprising a shaft (702); an initially cylindrically shaped delivery member (706); a therapeutic agent delivery lumen (710) connected to a therapeutic agent source; a retention member (704); and a therapeutic agent source being a syringe which is capable of applying negative pressure.
>
> Clark et al. disclose the claimed invention except for the delivery member being shaped in a continuous solid cylindrical configuration. Ding et al. teach in Figures 2 and 3 that it is known to use a delivery member having a continuous solid cylindrical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clark et al. with a continuously solid delivery member, since such a structure would ensure maximum contact with the treatment area when the delivery member is in its expanded state.
>
> Final Office Action, 5/28/2008, page 2, no. 1

Applicants disagree.

Independent claim 25 recites a medical device for delivering a therapeutic agent to an internal portion of a patient's body that includes, among other features, a self-expanding delivery member being shaped in a continuous solid cylindrical configuration from a porous material.

Clark et al. disclose "[a] catheter is disclosed comprising self-expandable delivery members which are compressed while the catheter is advanced to a site within a lumen, such as an artery or a vein, for example. When released at a desired site, the delivery members flare toward the wall of the lumen to deliver drugs or other agents proximate the wall." Summary of the Invention, column 2, lines 54-59. Delivery lumens provide drugs to ports in the delivery members for delivery out of the catheter. See column 2, lines 60-66.

Ding et al. disclose, Figures 2a and 2b, a catheter comprising "… an expandable portion 2 having a reservoir 12 disposed about a balloon 3 …. The reservoir 12 is connected to reservoir lumen 11 which can be used to fill the reservoir 12 with the drug 5. A porous membrane 13 defines the reservoir's outer surface. A sponge coating 4 having voids 10 therein covers the outer surface of the reservoir 12, i.e., outside the porous membrane 13." Column 3, lines 57-65.

Ding et al. disclose, Figure 3, "… a catheter 1 … wherein the balloon 3 and reservoir 12 of the embodiment of FIGS. 2a and 2b are combined. In this embodiment, drug 5 is placed into the balloon 3 through the inflation lumen 6 to expand the balloon 3 … by filling the balloon 3 with a fluid or composition containing drug 5, the balloon is expanded. The force of expansion causes the drug 5 in the balloon 3 to infuse the drug 5 into the voids 10 of the sponge coating 5. By expanding the balloon 3 further the drug 5 can be released from the sponge coating 4 …" Column 4, lines 27-38.

Ding et al. fails to disclose that the balloon being shaped in a solid cylindrical configuration of a porous material.

a. No *prima facie* obviousness

Prima facie obviousness under 35 U.S.C. §103 requires that the combination of references teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

As admitted in the Final Office Action, Clark et al. fail to disclose the delivery

member being shaped in a continuous solid cylindrical configuration as recited in Applicants' independent claim 25.

Ding et al. disclose that the balloon may be formed with pores and a sponge coat. "The balloon is filled with a biologically active material. When the balloon is inflated, the biologically active material infuses into the voids of the sponge coat and can be released into the body lumen." Column 2, lines 28-34.

Ding et al. do not disclose, however, that the balloon is a continuous solid cylindrical configuration.

One of ordinary skill in the art would understand the Ding et al. balloon to be the standard catheter balloon as was the state of the art at the time of Ding et al. See, for example, US 5,304,121 to Sahatjian and US 5,120,322 to Davis et al., both which are cited by Ding et al. in the Background of the Invention.

Without more, Ding et al. lacks any disclosure of a solid cylindrical delivery member as recited in independent claim 25.

At most, the combination may lead one of skill in the art to provide the delivery members of Clark, which are preferably integral with, and formed from the same material as the catheter shaft (column 6, lines 3-5), with the sponge coating of Ding et al.

The combination simply fails to lead one of skill in the art to a solid cylindrical delivery member, and no *prima facie* showing of obviousness has been established with respect to claim 25. Claims 26-40 depend from claim 25 and are not obvious for at least the reasons that claim 25 is not obvious over Clark et al. in view of Ding et al.

b. No articulated reason why one of ordinary skill in the art would modify the Clark et al. device with the Ding et al. expandable portion or visa-versa without hindsight

In the Final Office Action, page 2, Applicants are specifically referred to Figures 24-26 of Clark et al. for "... a medical device comprising a shaft (702); an initially cylindrically shaped delivery member (706); a therapeutic agent delivery lumen (701) connected to a therapeutic agent source; a retention member (704); and a therapeutic agent source being a syringe which is capable of applying negative pressure." Final Office Action, page 2, no. 1.

In this embodiment, however, it must be noted that the shaped delivery member (706), is actually a plurality of longitudinal ribs, each of which comprises an independent lumen:

> FIGS. 24-26 illustrate a catheter 700 with an expandable distal portion ... The distal portion preferably comprises a plurality of longitudinal ribs 706 having proximal and distal ends depending from the shaft 702. Other configurations, such as overlapping ribs, can also be used. A central portion of the ribs 706 flare radially beyond the outer diameter of the catheter shaft, between the proximal and distal ends of the ribs 706. A portion of the ribs 706 preferably bear against the wall of the vena cava, as shown in FIG. 24. As above, the diameter D of the ribs 706 in their fully flared position, measured across the center of the outer periphery of a region defined by the ribs, as shown in FIG. 25, is preferably greater than the diameter of the site, ensuring that the ribs bear against the wall, as shown in FIG. 24.
>
> The longitudinal ribs 706 can be of any desired length, and preferably vary between 6-10 mm. The greatest diameter D of the longitudinal ribs 706 when fully flared is preferably 1.5-2 times their length L, as shown in FIG. 25. Eight lumens are provided in this embodiment, but more or less can be used, depending on the size of the lumen or vessel at the site of interest.
>
> At least one and preferably a series of ports 708 are provided in each rib 706. Delivery lumens 710 provide drugs or other agents to the ports 708, as shown in FIG. 25.
>
> Col. 13, lines 45-67 to col. 14, lines 1-9

FIG. 25 of Clark et al. has been reproduced below to illustrate the plural rib design:

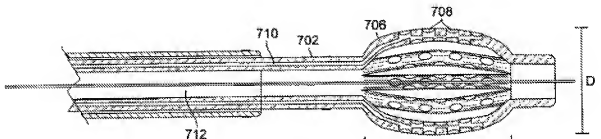

FIG. 25

Clark et al. discloses the reason for such a plural rib design as opposed to a single tubular member, is as follows:

Clark et al. discloses the reason for having a plurality of ribs, rather than a single tube, is as follows:

> It is known that the velocity of fluid flow through a tube varies across the axial cross-section of the tube. The velocity is maximum at the center of the tube and approaches zero at the walls. In an artery or a vein, blood flow is very slow in the region proximate the walls. If drugs or other agents could be effectively delivered proximate the walls, the blood or other fluid flow can atraumatically carry the delivered drug or agent over the site of interest. The delivered drug or agent would also not dissipate as rapidly as drug delivered at the center of the vessel. Less drug could then need to be delivered, shortening procedures and decreasing their cost.
>
> A drug delivery device which could deliver drugs proximate the walls of the vessel without blocking blood flow, would be advantageous.
>
> Background of the Invention, column 2, lines 35-51

In the Office Action mailed December 12, 2007, it was asserted that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clark et al. with a continuously solid delivery member, since such a structure would ensure maximum contact with the treatment area when the delivery member is in its

expanded state." Office Action, 12/12/2007, page 2 (bottom) to page 3 (top).

This analysis, based on Clark et al.'s own disclosure, is erroneous and is insufficient to establish a case of prima facie obviousness. Rather, MPEP 2142 discusses the legal concept of *prima facie* obviousness and articulates how the obviousness determination is to be made:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR International Co. v. Teleflex Inc.,* 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007).

Thus, the reasoning set forth in the Office Action dated 12/12/2007, is insufficient for establishing a proper showing of *prima facie* obviousness.

Applicants' previous argument included the statement that "[m]odifying the device of Clark to contain a delivery member, with a continuous solid cylindrical configuration would block blood flow, contrary to an express feature and purpose of the device disclosed by Clark." Response, 7/23/2008, page 5, bottom.

A different analysis was then presented in the Final Office Action dated 5/28/2008, in opposition to that previously set forth in the non-final Office Action. Here, the assertion was the following:

> … it would have been obvious to combine the references of Clark and Ding, because it is the shaft structure in combination with a therapeutic agent delivery lumen, initially cylindrically shaped delivery member, therapeutic agent source, retention member, and syringe of Clark that one of ordinary skill in the art would be looking to combine with Ding's device NOT the delivery member itself of Clark's device. The Clark reference is used to teach that such a system is known to advance delivery member to an internal portion of a patient's body, and thus it would be obvious to put the continuous solid cylindrical delivery member of Ding on Clark's device, irregardless of the fact that the device Clark uses is not a continuous solid cylindrical delivery member.
>
> Final Office Action, Response to Arguments, pp.3-4

Again, however, this analysis does not articulate a reason as to why one of ordinary skill in the art would make such a modification without the use of impermissible hindsight.

For example, the Clark et al. device (Figures 24-26 to which the Final Office Action refers), comprise, in the shaft, a plurality of delivery lumens 710 for providing drugs or other agents to the ports 708. This for the purpose of supplying the plurality of delivery members with therapeutic agent. Therefore it would be unclear as to why the Clark et al. shaft would be combined with the single delivery member such as provided by Ding et al. as asserted in the Office Action. Again, it is not clearly articulated as to why such a modification would be made as required for a proper determination of obviousness under 35 U.S.C. §103(a).

Thus, this analysis can only be based on impermissible hindsight. The Supreme Court in KSR, articulated that there still must be some reason articulated as to why the combination would be made, without the benefit of hindsight.

> b) The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was,

> independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. Helpful insights, however, need not become rigid and mandatory formulas. If it is so applied, the TSM test is incompatible with this Court's precedents.
>
> *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1389 (2007).

Also, under the *KSR* analysis, one of ordinary skill in the art must not only be able to implement a predictable variation, one must readily recognize a benefit to doing so. *KSR International Co. v. Teleflex Inc.,* 82 USPQ2d at 1389.

Therefore, no sufficient reason for a determination of obviousness has been presented, and thus no *prima facie* showing of obviousness has been established with respect to claim 25, and claims 26-40 which depend therefrom.

c. Even if prima facie obviousness could be established, teaching away is sufficient for rebuttal of *prima facie* obviousness

Clark et al. actually teach away from employing the single expandable balloon member of Ding et al.

As discussed above, the Clark et al. delivery member is in fact a plurality of delivery members 502 or with spaced ribs 702. The members or ribs of Clark are intended to allow the device to serve as a thrombolytic filter. The ribs can be solid or can define a series or ports or lumens (column 12, lines 6 1-65), but in any case they are configured to allow blood to flow to tissue distal to the delivery site through the regions defined by the ribs (column 14, lines 38-40). If the device is modified to contain a delivery member with a continuous solid cylindrical

configuration without gaps between ribs, it would no longer allow for blood to reach tissue distal the delivery site and would no longer perform act as a filter.

As discussed above, in the Background of the Invention, Clark et al. state:

> It is known that the velocity of fluid flow through a tube varies across the axial cross-section of the tube. The velocity is maximum at the center of the tube and approaches zero at the walls. In an artery or a vein, blood flow is very slow in the region proximate the walls. If drugs or other agents could be effectively delivered proximate the walls, the blood or other fluid flow can atraumatically carry the delivered drug or agent over the site of interest. The delivered drug or agent would also not dissipate as rapidly as drug delivered at the center of the vessel. Less drug could then need to be delivered, shortening procedures and decreasing their cost.
>
> A drug delivery device which could deliver drugs proximate the walls of the vessel without blocking blood flow, would be advantageous.
>
> Background of the Invention, column 2, lines 35-51

Thus, based on the above, while Clark certainly teaches away from any modification that would require the delivery member to be configured in the manner recited in the instant claims, it is also apparent that a modification forcing Clark to incorporate a delivery member having a continuous solid cylindrical configuration would interfere with the stated function of the Clark device. Simply put, one of ordinary skill in the art would not seek to structurally modify the filter of Clark in such a way that it is no longer capable of acting as a filter.

Secondary considerations, such as a teaching away from, are sufficient to overcome a *prima facie* showing of obviousness. Id. at 1390.

See also MPEP 2145 wherein it is stated that "[i]t is improper to combine references where the references teach away from their combination." MPEP, 8th Ed. Rev. 6 (Sep. 2007) §2145(X)(D)(2); see also *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. 1740 (2007); *Takeda Chem. Indus., Ltd. v. Alphaphann Pty. Ltd.,* 492 F.3d 1350, 1358-59 (Fed. Cir. 2007) (finding the prior art taught away from the claims and the claims therefore were not invalid). Clark clearly

shows and describes multiple delivery members or ribs (see elements 502 and 706 for examples) which collectively act as a filter to allow blood to flow therethrough while catching or removing a thrombus or plaque (column 12, lines 6 1-65 & column 14, lines 39-43). The filter described in Clark is clearly distinct from the continuous solid cylindrical member of the present application in both structure and function; regardless of the teaching of Ding, one of ordinary skill would have no reason to modify such a filter in a manner that would render the filter incapable of functioning as such.

To that end, in must also be noted that MPEP § 2143.01 states "If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." In the present case there is no doubt that the Examiner's proposed modification of Clark would render the described filter unsatisfactory for its intended purpose.

Again, Applicants assert that it would not be obvious to one having ordinary skill in the art to modify the device of Clark et al. to contain a delivery member with a continuous solid cylindrical configuration such as instant claims 25 recites. Claims 26-40 which depend therefrom are also not obvious for at least these reasons.

CONCLUSION

For at least the reasons discussed above claims 25-40 of the instant application, are patentably distinct over the cited art.

Based on the foregoing, claims reversal of the rejection of claims 25-40 under 35 U.S.C. §103(a) as being obvious over Clark et al. (US 5,713,853) as modified by Ding et al. (US 6,364,856) is respectfully requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 25 2008

By: /Lisa Ryan-Lindquist/
Lisa R. Lindquist
Registration No.: 43071

6640 Shady Oak Road, Suite 400
Eden Prairie, MN 55344
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\lrl\14157US01_appealbrief_20081104.doc

viii. Claims appendix

25. A medical device for delivering a therapeutic agent to an internal portion of a patient's body, the medical device comprising:

a shaft;

a self-expanding delivery member in operative communication with the shaft, the delivery member having a proximal end and a distal end and being shaped in a continuous solid cylindrical configuration from a porous material capable of (i) releasing the therapeutic agent to the internal portion of the patient's body and (ii) being in a collapsed state;

a therapeutic agent delivery lumen defined by a lumen wall, wherein the therapeutic agent delivery lumen is in fluid communication with the delivery member for fluidly connecting the delivery member with a therapeutic agent source;

a retention member in operative communication with the delivery member, the retention member being configured and arranged to selectively collapse the delivery member; and

a mechanism capable of applying negative pressure through the therapeutic agent delivery lumen to remove fluid from the delivery member.

26. The medical device of claim 25, wherein the therapeutic agent source is a Luer syringe.

27. The medical device of claim 26, wherein the Luer syringe is the source of the negative pressure.

28. The medical device of claim 25, wherein the delivery member is formed of carboxymethyl cellulose, polyacrylic acid, carboxymethyl starch, chitosan, potassium polymetaphosphates, polyethylene, nylon, polyurethane, PEBAX, silicone, alginate, cotton, polymers cross-linked during phase transition, collagen foams, PLA, PLGA, or PGA.

29. The medical device of claim 25, wherein the porous material is degradable.

30. The medical device of claim 25, wherein the delivery member is shaped from a self-expanding material that is configured and sized to contact at least a portion of a target body lumen when the delivery member is in an expanded state.

31. The medical device of claim 30, wherein the delivery member is configured and sized to self-expand to at least partially conform to the internal contour of the target body lumen when the delivery member is in an expanded state.

32. The medical device of claim 25, further comprising a distal end cap disposed at the distal end of the delivery member, the distal end cap at least partially sealing the distal end of the delivery member.

33. The medical device of claim 25, further comprising a proximal end cap disposed at the proximal end of the delivery member, the proximal end cap at least partially sealing the proximal end of the delivery member.

34. The medical device of claim 25, wherein the proximal end of the delivery member has a tapered configuration when the delivery member is in an expanded condition.

35. The medical device of claim 25, wherein the distal end of the delivery member has a tapered configuration when the delivery member is in an expanded condition.

36. The medical device of claim 25, wherein the delivery member has a length between about 5mm and about 40mm.

37. The medical device of claim 25, wherein the shaft has a wire lumen therethrough for receiving a guide wire.

38. The medical device of claim 37, wherein the wire lumen is located within the delivery lumen.

39. The medical device of claim 37, wherein the wire lumen extends into the delivery member.

40. The medical device of claim 25, wherein the mechanism capable of applying negative pressure is a Luer syringe.

(ix) Related Proceedings Appendix

None

(x) Evidence Appendix

None